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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/713,008	11/17/2003	Masaaki Ikeda	64517.000002	5744

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EXAMINER	
MAKAR, KIMBERLY A	

ART UNIT	PAPER NUMBER
1636	

MAIL DATE	DELIVERY MODE
03/30/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action Before the Filing of an Appeal Brief	Application No.	Applicant(s)	
	10/713,008	IKEDA ET AL.	
	Examiner	Art Unit	
	Kimberly A. Makar, Ph.D.	1636	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 06 March 2007 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☒ The period for reply expires 5 months from the mailing date of the final rejection.
   b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: _____.
   Claim(s) objected to: _____.
   Claim(s) rejected: *1,2,4,6 and 16-19*.
   Claim(s) withdrawn from consideration: *7-15*.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See continuation sheet.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08) Paper No(s). _____
13. ☐ Other: _____.

DAVID GUZO
PRIMARY EXAMINER

Continuation of 11. does NOT place the application in condition for allowance because: Claims 1-2, 4, 6, and 16-19 are rejected under 112 1st scope of enablement. The current claims read on a method of proliferating any terminally differentiated cell either in vivo or in vitro by deliverying a D-type cyclin and the cyclin depedent kinase CDK4 or CDK 6 to the nucleus of the cell, but are only enabled for a method of proliferating cardiomyocytes in vitro by introducing adenoviral vectors expressing a D-type cyclin, CDK4 or CDK6 and a nuclear localization signal. The current amendment, limiting the cell types of the method to cardiomyocytes in claims 1-2, 6, and 16-19 only addresses a portion of the enablement rejection, and does not overcome the rejection regarding the lack of enablement for in vivo methods or using any vector.

Applicants point to the specification and example 5 as an example enabling for in vivo work (see applicant's reponse dated 3/6/07). This example is not enabling for all in vivo work. This method is a sole example of in vivo work where applicant utilizes adenoviral vectors that are injected directly into the apex of a rat heart. Data looking at proliferation marker, Ki-67, was investigated at a single timepoint after 4 days. There is no disclosure of how many cells the adenoviral vector was capable of infecting, if the adenoviral vector only infected cardiomyoctes, how long the proliferation lasted, or any other in vivo model. How many new cells or multinucleated cells were produced in vivo? Thus the lone example is not enabling for all in vivo work.

Applicants also point out that current claim 6 limits the method to adenoviral vectors (see applicant's response dated 3/6/07). This however, does not address the issue of the type of vector used in base claims 1 and 2, which still read on a method for the proliferation of cardiomyocytes using any vector. Applicants only show and teach their method utliizing adenoviral vectors. Thus the claims which are not limited to in vitro work and adenoviral vectors are not in condition for allowance.